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INTERNATIONAL APPLICATION PUBLISHED PURSUANT TO THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification[6]: A61C 13/30

A1

(11) International Publication No.: **WO 96/15731**

(43) International Publication Date: May 30, 1996 (05/30/96)

(21) International Application Number: PCT/FR95/01533

(22) International Filing Date: November 21, 1995 (11/21/95)

(30) Data Related to Prior Art:

94/14183 Nov. 21, 1994 (11/21/94) FR

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(81) Designated Countries: AU, BR, CA, CN, JP, KR, MX, PL, RU, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:

With international research report.
The application will be re-published prior to expiration of the time frame allowed for changes to the claims, if such changes are received.

(54) Title: CROWN-AND-ROOT RECONSTRUCTION ASSEMBLY MADE OF A COMPOSITE MATERIAL WITH A MODULUS OF ELASTICITY VARYING ALONG A GRADIENT, AND METHOD FOR MAKING SAME.

(54) Title: [same as above in French]

(57): Abstract

A crown-and-root reconstruction assembly made of a composite material with a modulus of elasticity varying along a gradient. The assembly comprises a physiological securing peg (4) and a crown reconstruction base (1) made of partially or completely light-conducting material. The connection between the crown reconstruction base (1) and the peg (4) is achieved by polymerizing the material of the base under an isostatic charge. The forming process may be completed by manipulating the material with the fingers through a forming membrane (22) to prevent any gap developing at the interface (10) between the root (8) and the crown reconstruction base (1). A helical arrangement of the fibers (5) of the peg (4) ensures that the modulus of elasticity is close to that of the natural dentine, regardless of the angle of incidence at which the

Crown-and-root reconstruction assembly made of a composite material with a modulus of elasticity varying along a gradient and method for making same.

Prior Art

This invention deals with a crown-and-root reconstruction assembly for a dental prosthesis, comprised of a physiological securing peg and a crown reconstruction base made of composite material tightly connected to the peg and applied without any gap to the tooth or to a laboratory model reproduction of the healthy remaining portion of the tooth.

In dentistry, crown-and-root reconstructions generally use pegs made out of various metallic alloys that are either prefabricated or cast via indirect technique. The use of metallic pegs presents many disadvantages resulting from electro-chemical corrosion and oxidation phenomena or from the clustering of metallic ions in the body. When the crown reconstruction base is cast simultaneously with the peg, the crown-and-root reconstruction assembly is homogeneous but its mechanical behavior is far from that of a natural tooth, a fact which results in root fractures in reconstructed teeth.

Pegs made out of composite material are also available, in particular those made from high solidity fibers that may possibly be included in organic matrices as composite materials. Such pegs are described in documents FR-A 2588181 and EP-A-432001. The reconstruction base is made directly inside the mouth on the natural tooth, with a charged resin or ionomer glass. A carbon fiber and epoxy resin peg has a modulus of elasticity (110 GPA) that is identical to that of titanium when it is stressed along the axis of the fibers. The pegs can be fabricated by machining cylindrical bars or they can be made from axial carbon fibers assembled in an organic matrix.

The method consists of lining what remains of the tooth to be reconstructed and inserting the reconstruction product in a pasty state using a spatula or with the fingers. The reconstruction product is composed of two pastes to be mixed at the time of use and one of the two pastes includes the catalyst. However, in mixing the two pastes, there is the risk of air bubbles becoming incorporated in the mixture, which results in inhibiting the polymerization around each bubble, thus creating areas in which there remain free monomers that are toxic to dental tissues. These poorly polymerized areas are the source of a significant reduction in the reconstruction's mechanical qualities and are choice areas for discolorations and bacterial growth; they are also a source of cracks and fractures. The [illegible] control of the components' proportions, which [illegible]

[illegible] the product used is very thick. Indeed, the degree of polymerization of a resin is inversely proportionate to the square of the distance to the light source.

When the reconstruction material is manually inserted, the reconstruction paste must have characteristics that allow for easy handling. The resin must be charged with particles or ultra short fibers so that the material retains some viscosity and pegosity in order to ensure easy manual handling. The mechanical characteristics of such a material are weak, with the modulus of elasticity usually in the 4 to 12 Gpa range and tensile resistance does not exceed 60 to 70 Mpa.

Inventors have determined that in a crown-and-root reconstruction assembly, the root dentine, the favored locus for fractures, must be stressed as little as possible. The peg must be in a passive state and its role is to maintain the crown portion of the reconstruction base. In the case of a metallic peg, in particular a titanium peg, or of a peg made of carbon-epoxy fibers, the application of evenly spread pressure on the occlusal face of a root reconstruction causes deformation of the base of the charged resin root reconstruction with a low modulus of elasticity (4 to 12 Gpa). The peg will very quickly have to support the entire load, with the risk that it may cause the root to explode in the event of significant pressure on the tooth, particularly when the force is applied along the axis of the fibers that coincides with the axis of the peg and the tooth.

The method of inserting resins charged with particles inside the mouth, a task performed with a spatula or with the fingers and done directly on the peg that has been previously sealed into the root, may result in separations between the dentine and the reconstruction base interface. This gap is due to the inevitable contractions that occur during polymerization of organic matrices and it will be the infiltration point which will threaten the crown-and-root reconstruction's longevity.

Purpose of the Invention

This invention seeks to remedy these disadvantages and involves making a crown-and-root reconstruction assembly with great solidity, independently from the angle of incidence of the force applied to the tooth.

The crown-and-root reconstruction assembly pursuant to the invention is characterized by the fact that:

- the connection between the crown reconstruction base and the peg is achieved by polymerization of the material of said base under an isostatic charge, after placing an auxiliary forming part in the upper part of the base,
- and the majority of the fibers that reinforce the peg are more than 3 mm long and run in a different direction from that of the longitudinal axis of the peg so as to adjust the peg's

[illegible] MPa

The presence of long fibers in the composite material of the crown-and-root assembly

produces a modulus of elasticity in the 15 to 50 GPa range.

Obtaining a constant and uniform resin/support ratio is the result of an isostatic pressure on the reconstruction base. This leads to a pressing effect which brings the different fibers closer together and releases a certain amount of resin in order to reach the resin/support ratio calculated so as to obtain the modulus of elasticity sought, i.e., 15 to 50 GPa. With the same forming process pressure, the same resin rate is maintained for each reconstruction, along with the same mechanical characteristics.

The identity of the modulus of elasticity of the peg and the dentine helps achieve a harmonious flow of mechanical stresses and an absence of stress concentration at the interfaces, in particular at the apical end of the peg. Dentine's modulus of elasticity varies from 9 Gpa in the root portion to 20 Gpa in the crown portion. The particular organization of the long fibers that reinforce the peg helps adjust the peg's modulus of elasticity to that of the tooth dentine from the crown portion of the peg (20 Gpa) to the root portion (9 Gpa). In order to avoid the nail effect that might cause the root to explode, the axis of the majority of the peg's fibers is along a gradient in relationship to the longitudinal axis of the peg, which corresponds to the axis along which masticatory forces are applied.

The consequence is that the root peg must also have a modulus of elasticity that is close to that of the crown-and-root dentine, in order to avoid significant changes in the modulus of elasticity which would impede the harmonious flow of stresses across the interfaces.

According to one characteristic of the invention, the fibers of the peg are arranged in a helical fashion, either crossed or not crossed, woven or unwoven, where the diameter of the turns and the threading are calculated according to the finite elements method. The long fibers used can be chosen among any high performance fibers, in particular fiberglass E or R, carbon, ceramic, silicon carbide, boron carbide, aramid.

According to another characteristic of the invention, the central core of the peg can be made out of a material easily penetrable via mechanical or chemical means and that will serve as a guide for dental instruments during removal of the peg, particularly at the time of a subsequent dental work on the root.

The fiber/resin ratio, the diameter, the length and number of fibers from the crown portion to the apical portion of the peg are calculated so that the modulus of elasticity of the peg will vary from 9 Gpa to 20 Gpa +/- 40%, regardless of the angle of incidence of the force that [illegible]

[illegible] controlled under laboratory conditions with powerful lighting that guarantees maximum resin conversion rate as well as the homogeneity sought.

Description of the Diagrams

Other advantages and characteristics will appear more clearly from the following description of an embodiment of the invention given only by way of example, without any limitation thereto. The embodiment is represented in the diagrams appended hereto in which:

- figure 1 is a cross-section of a portion of the tooth equipped with a pressure device in order to make the crown-and-root reconstruction assembly according to the invention;

- figure 2 shows a schematic view of the peg represented in figure 1 on a larger scale;

- figure 3 is a view identical to figure 2 of an embodiment variation of the peg;

- figure 4 is a view identical to figure 1 of an embodiment variation using a vacuum device;

- figure 5 represents a cross-section of the tooth equipped with a dental prosthesis crowning the crown-and-root assembly according to the invention;

- figure 6 is a cross-section of another type of peg;

- figure 7 shows another system for shaping the crown-and-root reconstruction assembly.

Description of a Preferred Embodiment

In figure 1, the crown-and-root reconstruction assembly features a crown reconstruction base 1, made out of a composite material that includes an initial reinforcement of fibers 2, sunk in an initial matrix 3 and connected to a physiological root peg 4. Peg 4 is also made out of a composite material equipped with a second reinforcement of fibers 5, sunk into a second matrix 6. Peg 4 is lodged axially in a central hole made in the residual root or dentine 8 and the crown reconstruction base 1 rests on the upper face of the root 8.

According to the invention, the helical structure (figure 2) of the second fiber reinforcement 5, associated with a predetermined variation of the diameter of the helicoid, of the threading, of the nature, diameter and rate of fibers, of their crossing or weaving, has made it possible to make peg 4 out of a composite material with a modulus of elasticity that is always comparable to that of natural dentine and that never varies from it by more than 40%, regardless of the angle of incidence of the force stressing peg 4. The result is that there are no mechanical stresses at the interfaces of peg 4 and dentine 8, in particular at the apical

[illegible]

[illegible] polyurethane, polyester, acrylic or methacrylic.

The organic matrix 6 of peg 4 may also be charged with organic, mineral or metallic particles, designed to change its pegosity, viscosity, surface state and the bio-compatibility of peg 4. The surface state of the top side of peg 4 allows for optimal gluing of peg 4 to dentine 8 according to gluing techniques known in the art.

The majority of the reinforcement fibers 5,2 of peg 4 and of reconstruction base 1 are never entirely stressed along their large axis. The modulus of elasticity of peg 4 is always close to that of dentine 8 and the modulus of elasticity of the reconstruction base 1 is always equal to or greater than that of the crown dentine, independently from the angle of incidence of the force applied to the reconstruction.

The process of shaping the paste of which reconstruction base 1 is made is done by applying isostatic pressure exerted after molding a membrane or bladder of a forming device.

An auxiliary intermediate forming part 7 is advantageously applied to the upper surface of the reconstruction paste and can be either circular or ellipsoidal in shape. The material of intermediate part 7 is transparent to light rays and may be moldable. Forming part 7 is equipped with a dummy positioning hole 11 located straight to peg 4 and may be joined to the reconstruction paste 1 content.

Forming part 7 is formed according to a piston with a short sliding stroke that also serves as a stop at the upper end of peg 4. The paste for reconstruction base 1 comes as a cylindrical or tapered preform which before polymerization is in a paste (prepegg [sic]). It may possibly be included in a case that is part of forming part 7 and is translucent and moldable. It is also possible to incorporate it inside a syringe or some other opaque container that allows for preservation and application of the paste in order to make the reconstruction.

The preform is positioned on peg 4 and is then covered by intermediary part 7. The forming devices are then implemented as are the polymerization devices. After polymerization, forming part 7 is removed so as to expose the upper face of the reconstruction base 1 and the projecting end of peg 4.

In the case of figure 1, forming the crown-and-root reconstruction assembly may be achieved inside the patient's mouth. A housing 13 covers the crown-and-root reconstruction assembly and contains an inflatable bladder 14 connected to an appropriate device 15 for injecting fluid at a determined temperature and pressure. The illumination needed for photo-polymerization is then achieved by way of a light guide that can be made from a fiber optic 16.

[illegible]
inside the internal space 24 so as to coat membrane 22 on intermediary shaping part 7, reconstruction paste 1, peg 5 and the replica of residual root 8, during the polymerization

phase by the rays generated by the fiber optic 16. Forming part 7 is then discarded at the end of the polymerization phase.

This forming method in a vacuuum may, of course, be implemented inside the patient's mouth.

The physical behavior of reconstruction base 1 may also be improved by completing the forming process during application of the isostatic pressure, with finger manipulation through membrane 22, thus avoiding any gap at the interface 10 of root 8 and crown reconstruction base 1.

At the end of the polymerization operation, the crown-and-root reconstruction assembly is homogeneous and features a modulus of elasticity that is adapted to the tooth's functional and protective needs, and there is no gap at reconstruction interface 10.

As for figure 5, after removal of the auxiliary forming part 7, the reconstruction base 1 is covered by a prosthesis that has a high modulus of elasticity, specifically a metallic or ceramic crown 25, with insertion of a support shell 26 described in document WO 95/08300.

The shell 26 serves as an interface and constitutes a intermediary transitional layer between the rigid crown 25 and the residual tooth 8. This layer is made out of composite material. This shell 26 features a modulus of elasticity close to that of natural dentine and helps dampen shocks.

The prosthesist glues the shell 26 in the laboratory in the lower side of the metallic or ceramic crown 25 and then, in the dentist's office, the dentist performs the process of gluing the crown 25 covered on the reconstruction base 1 with the same type of resin as that used in the formulation of the composite materials for the base 1 and the shell 26.

Peg 20 according to figure 3 is obtained by machining sheets or sections of composite material where the fiber organization is three-dimensional following axes x, y or z. The tooling axis a, a' of peg 20 never uses axes x, y or z and forms an alpha angle of 20° to 70° with axes x, y, z.

As for figure 6, the central core of peg 4 can be made from a material that is easily penetrable either chemically or mechanically, in order to act as a dental instrument penetration guide, particularly for drills and files, avoiding lateral perforations. The core 28 may be transparent and in this case serves as a light guide.

[illegible] vacuum pump via a connecting tube 30. After the peg 4 has been positioned, the reconstruction paste 1 is then applied on the residual root 8 and the forming part 7 is

positioned on top of the paste 1.

A watertight mould 31 covers the assembly; it is made from a moldable and transparent material 32, in particular from photo-polymerizable elastomer. The mould 31 ensures peripheral water-tightness and is molded under vacuum conditions in order to exert the isostatic pressure when the crown reconstruction base 1 undergoes the forming process. Then, a light source induces photo-polymerization of the reconstruction base 1 through forming part 7 and the material 32 of mould 31, while maintaining the isostatic pressure.

CLAIMS

1. Crown-and-root reconstruction assembly for a dental prosthesis, including a crown reconstruction base (1) made from a composite material with an initial reinforcement of fibers (2) sunk in an initial matrix (3) and connected to a physiological root peg (4) also made from a composite material equipped with a second reinforcement of fibers (5) sunk into a second matrix (6), where said crown reconstruction base (1) rests on the upper face of the root (8) after the root peg (4) has been inserted inside a hole in said root.
Characterized in facts that:
- the connection between the crown reconstruction base (1) and the peg (4) is achieved by polymerizing said base (1) material under isostatic charge, after placing an auxiliary forming part (7) on the upper part of the base,

- and the majority of the fibers (5) that reinforce the peg (4) are more than 3 mm long and have a different direction from that of the longitudinal axis of the peg (4) so as to adjust the modulus of elasticity of the peg (4) close to that of natural dentine, independently from the angle of incidence of the force applied to the tooth, with the assembly having a tensile strength greater than 200 MPa.

2. Crown-and-root reconstruction assembly according to claim 1, characterized in that the fibers (5) that reinforce the peg (4) are arranged in a helical structure with predetermined diameter and threading and/or rate of fibers along the crown portion to the root portion of the peg (4).

3. Crown-and-root reconstruction assembly according to claim 1, characterized in that the fibers (5) that reinforce the peg (4) are subject to a predetermined crossing or weaving.

4. Crown-and-root reconstruction assembly according to claim 1, characterized in that the fibers (5) that reinforce the peg (4) feature a three-dimensional organization, with the tooling axis (aa') of the peg (4) at an alpha angle ranging from 20° to 70° in relationship to each of the three axes (x, y, z).

5. Crown-and-root reconstruction assembly according to claim 1, characterized in that the fibers (5,2) that reinforce the peg (4) and reconstruction base (1) are made from materials that act as light guides.

6. Crown-and-root reconstruction assembly according to claim 1, characterized in that, after polymerization under isostatic pressure, the composite material that constitutes the crown

7. Crown-and-root reconstruction assembly according to claim 1, characterized in that the auxiliary forming part (7) is made out of a material that is transparent to light rays and that

can be disposed of after the photo-polymerization phase.

8. Crown-and-root reconstruction assembly according to claim 7, characterized in that the auxiliary forming part (7) has a dummy opening positioning hole (11) located straight to the peg (4) and placed along a piston with a short sliding stroke that also acts as a stop at the upper end of the peg (4).

9. Crown-and-root reconstruction assembly according to claim 1, characterized in that a support shell (26) made out of composite material is glued in the lower side of a crown (25) that is the dental prosthesis and the gluing process is achieved with a resin of the same nature as that of said shell (26) and the first matrix (3) and that the support shell (26) represents an intermediary transition layer that has a modulus of elasticity close to that of the natural dentine in order to help dampen shocks.

10. Forming process for a crown-and-root reconstruction assembly according to one of the claims 1 to 9, characterized in that:
- a preform is used as the paste for the crown reconstruction base (1) that is in a pasty state prior to polymerization and that is included in a case or a syringe,
- isostatic pressure is exerted through an elastic and translucent membrane (22) that is moldable when the internal space (24) is placed in a vacuum. The preform is coated, on the one hand, on the peg (4) and the interface (10) and, on the other hand, is formed via the fingers through the membrane (22).
- and the photo-polymerization is implemented by illumination of a light source, in particular by an optical fiber 16.

11. Forming process for a crown-and-root reconstruction assembly according to one of the claims 1 to 9, characterized in that, the isostatic pressure during polymerization is achieved via an enclosure (13) equipped with a bladder (14) that can be inflated by means of injecting a liquid (15) at a pre-determined temperature and pressure.

12. Forming process for a crown-and-root reconstruction assembly according to one of the claims 1 to 9, characterized in that:

- the upper portion of the residual root 8 is encircled with a pumping strand 29 connected to a vacuum pump,
- reconstruction paste 1 is applied to root 8 after positioning the peg 4,
- the forming part 7 is positioned on the upper part of the reconstruction paste 1,
[illegible] watertight mould 31 made from a photo-polymerizable and